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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,183	03/16/2001	Robert W. Kreis	CV-0275	5218

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,183	KREIS ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of Applicant's Amendment after Non-Final Office Action (to specification & claims), Applicant's Arguments/Remarks and the Associate Power of Attorney notice, all filed 10/21/05 is acknowledged.

The 35 U.S.C. §112, second paragraph rejections over claims 1-8 have been withdrawn, by virtue of Applicant's amendment.

Claims 1 and 9-12 are pending in this action. Claims 1 and 9 have been amended. Claims 2-8 have been cancelled. Claims 1 and 9-12 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlisle (U.S. Pat. No. 3,824,996).

The instant invention is drawn to a method of treating an acute wound using a wound dressing as a substitute for a biological dressing or skin graft comprising the steps of:

a) applying the wound dressing to the wound; and

b) allowing the wound dressing to adhere to the wound for a period of time effective to promote epithelial outgrowth and promote vertical wicking into the dressing, wherein the wound dressing comprises highly absorbent fibers.

Carlisle ('996) teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract).

According to Carlisle, the dressings have a finely porous, highly dense fibrous construction which provides the dual advantages of dispersing absorbed exudates to a low interlayer adhesion level, and preventing healing tissues from becoming entangled with the dressing's fibrous material (col. 3, lines 53-67). Carlisle teaches the significance of the speed of absorption, direction of absorption and the length of wicking (col. 4, lines 1-14). The chart at column 4 demonstrates that the dressing of Carlisle absorbs fluid steadily and continuously (i.e., wicking) (see col. 4, lines 15-55).

Carlisle teaches that the dressing layer materials can absorb distilled water vertically against gravity continuously for more than 5 hours (see claim 4). Carlisle also teaches that the dressing, when affixed and held in place with retaining material, adapts to exert relatively even

pressure on the wound surface which tends to improve the quality of the repair tissue formed during healing (claim 17).

The wound dressings can be applied to wounds, such as burns (col. 2, lines 63-67).

Suitable dressing materials taught includes hard and soft wood pulp (col. 5, lines 19-22) and fibrous dense cellulose materials (see claims 1, 5, 6, 18).

With regards to the claim limitation 'for a period of time effective to promote epithelial outgrowth and promote vertical wicking' recited in instant claim 1, the Examiner notes that this limitation is a future-intended use limitation, which affords no patentable weight to the claims.

With regards to the amount of water (25 g/g) claimed in claim 12, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is the position of the Examiner that the particular method of treating an acute wound using a wound dressing and applying the wound dressing to the wound would be obvious in view of the disclosure of Carlisle. Carlisle clearly teaches highly absorbent pressure dressings for wounds, such as burns, constructed from cellulosic, fibrous material, whereby the dressings are applied and affixed to curved surfaces of the human body.

Thus, given the teachings of Carlisle delineated above, the instant invention, when taken as a whole, would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 10/21/05 have been fully considered.

Firstly, Applicant argued regarding the 35 U.S.C. §112, second paragraph rejections over claims 1-8 stating, "Claim 1 has been amended to recite a method of treating an acute wound." Applicant's arguments are persuasive by virtue of the amendment. Accordingly, the 35 U.S.C. §112, second paragraph rejections over claims 1-8 have been withdrawn.

Secondly, Applicant argued regarding the 35 U.S.C. §102(b) rejections of claims 1-12 over three patents; Carlisle, Errede et al. and Ewall stating, "Applicant disagrees that claims 1-12 are anticipated by either Carlisle, Errede et al. or Ewall. Neither Carlisle, Errede et al. or Ewall anticipate the invention as claimed in claims 1, 9, 10, 11 or 12."

Applicant's arguments have been considered and were found to be persuasive. Accordingly the 35 U.S.C. §102(b) rejections of claims 1-12 over Carlisle, Errede et al. and Ewall have been withdrawn.

However, the instant pending claims (1 and 9-12) have now been rejected under 35 U.S.C. 103(a) as being unpatentable over Carlisle (U.S. Pat. No. 3,824,996). Carlisle, as delineated above, teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract). The reference recognizes and teaches the importance of 'wicking' and teaches high absorption of fluids. Examiner notes that the claim limitation 'for a period of time effective to promote epithelial

outgrowth and promote vertical wicking' recited in instant claim 1, denotes a future-intended use limitation, which, without structural limitation, affords no patentable weight to the claims. It is the position of the Examiner that the particular method of treating an acute wound and applying the wound dressing to the wound would be obvious in view of the disclosure of Carlisle. Applicants have not demonstrated any surprising or unexpected results, which accrue from the instantly claimed method steps. The prior art teaches similar wound dressings, made from similar components for use in the same field of endeavor as the Applicants. Furthermore, the method of applying those particular dressings would be deemed obvious based on the teachings of the prior art.

Hence, given the explicit teachings of Carlisle, the instant invention when taken as a whole, would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 1-12.

Patent Examiner

Art Unit 1615

January 09, 2006

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